Headquarters U.S. Air Force

Integrity - Service - Excellence

AFMS Group

21 Jul 04

1300-1530

U.S. AIR FORCE

U.S. AIR FORCE

AFMS Group Agenda

- **Approval of Minutes – Mr. Costa** **5 Min**
- **EOS – Dr. Tibbetts** **30 Min**
- **POM Offsets – Maj Speece** **30 Min**
- **OP Discussion – Mr. Gooding** **15 Min**
- **Open Discussion** **15 Min**

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Minutes Approval

- 30 Jun 04 AFMS Group Minutes – Approved?
- Archives of AFMS Corporate Structure minutes can be found at:
  - O:\SG_Common\AFMS Corporate Structure

    - or –
  - https://kx.afms.mil/afmsengineroom

Headquarters U.S. Air Force

Epidemic Outbreak Surveillance (EOS)

Scientific Briefing

AF/SGR
14 July 2004

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Integrity - Service - Excellence

Epidemic Outbreak Surveillance (EOS)

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- Purpose: Introduce EOS Program to AFMS Group
  - Classification: Unclassified
  - Type: Information
  - Length of Briefing: 30 minutes (anticipate 45 minute with discussion)
  - Briefer: Dr Clark Tibbetts, HQ USAF/SGR

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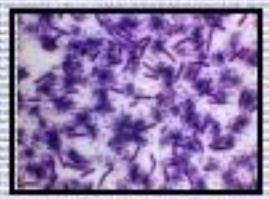
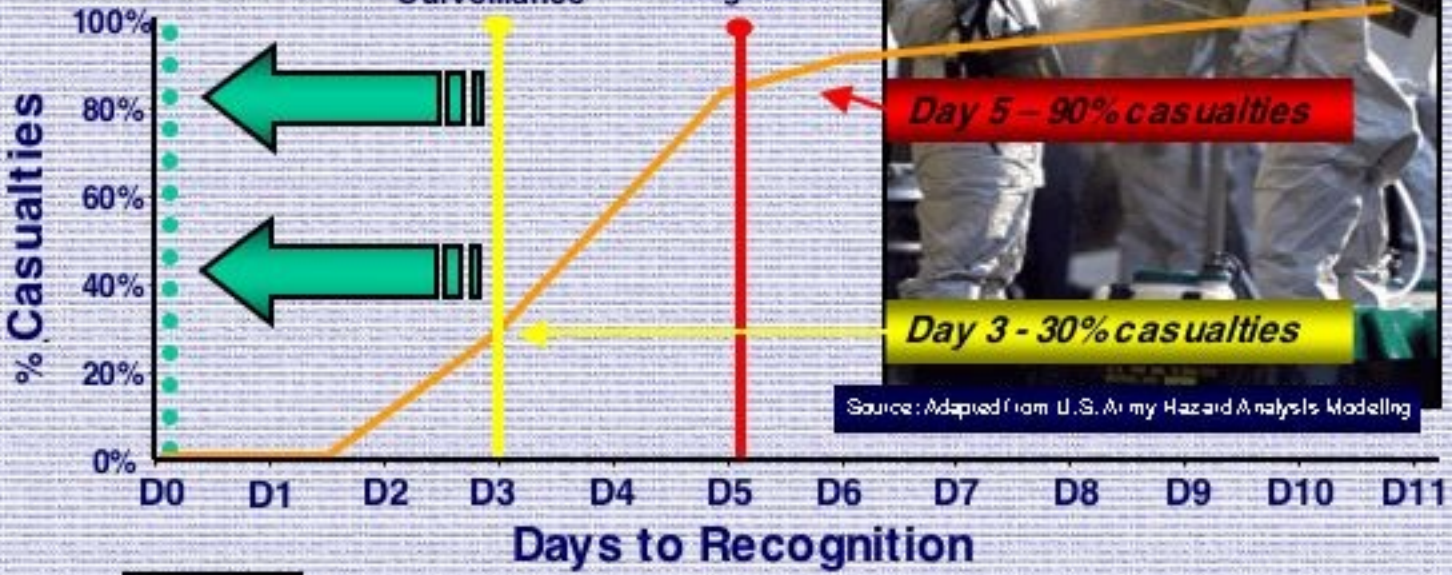
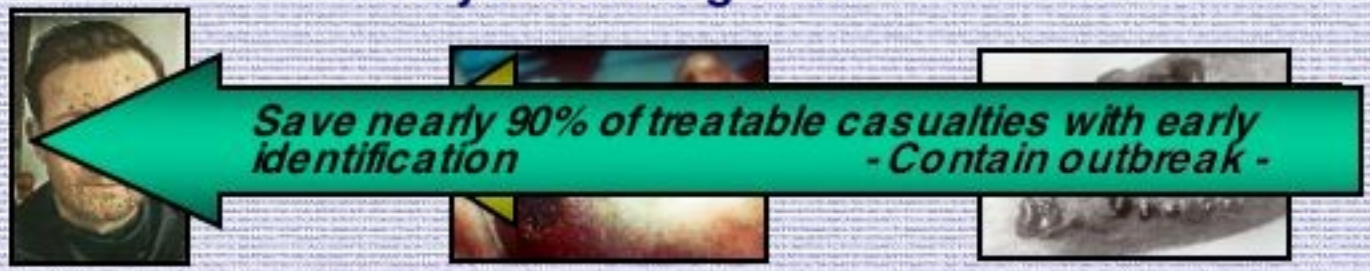
Epidemic Outbreak Surveillance

Making the Difference







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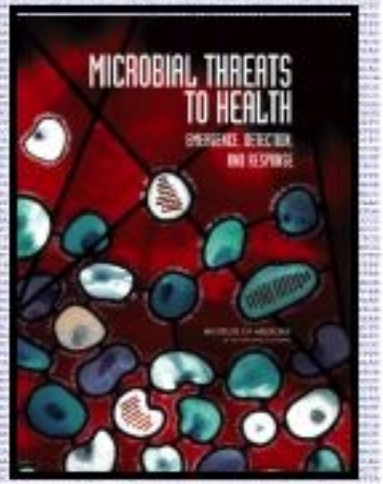
National Strategic Thinking

Roadmaps for Effective Biodefense

- **Guidance from highest levels of scientific and technical review**
  - Defense Science Board (DSB) Summer Study (2000)
  - Health Surveillance Biodefense System (HSBS) Report (2001)
  - National Academy of Sciences Institute of Medicine (2002)
- **Transforming vision of key elements required for effective biodefense**
  - Advanced diagnostic platforms - highly multiplexed, real time (z-chip)
  - Integrated diagnostics, network IT and (bio)informatics
  - Dual use applications - medicine/biodefense and military/civilian
  - Validation of performance in real world testbed venue
  - Proactive address of Ethical, Legal, Social Issues (ELSI)
- **Develop a biodefense system that detects to…**
  - Warn … Two hours – tests all pathogens
  - Treat … Early intervention saves 90% of force
  - Act! … Forensic capabilities for attribution



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AF Operationalization

F2T2EA Threat Response System of Systems

Air and Space Superiority

"From sensor... to strike... in single digit minutes."

General Jumper

Biodefense Superiority

Health Surveillance Biodefense System (HSBS)

Epidemic Outbreak Surveillance (EOS)

"... to recognize and combat a potential epidemic within the first three hours of its introduction into the population."

Lt Gen Taylor

Predictive Battlespace Awareness - Find	Surveillance Awareness - Find
Geolocate - Fix	Diagnose Geolocate - Fix
Prioritize - Sort - Track	Analyze - Prioritize Forensics
Strike Package	Target - Control Source Attribution
Clear to Engage - Weapons Launch	ELSI - Policy
Battle Damage Assessment	Real World Assessment

EOS Dual Use Investments

Line and DHP Cost Sharing

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OFFICE OF THE SECRETARY OF DEFENSE
1980 DEFENSE PENTAGON

1 November 2001

MEMORANDUM FOR DISTRIBUTION

SUBJECT: Exploring Biotechnology -- Opportunities for the Department of Defense

Over the last year my office has undertaken a study to examine the revolutionary potential that biotechnology might bring to the future of warfighting. The study looked at biotechnology in its broadest sense, from genetic research to systems engineering and organizational metaphors.

It is our belief that biotechnology, and its fusion with other new areas of science, holds revolutionary prospects for U.S. military capabilities. Embracing biotechnology in ways beyond our current expertise in bio-defense and medical applications would likely result in a strategic U.S. military advantage for the next several decades.

The study is organized to include a short historical perspective on the nature of revolutions in military affairs; a self-assessment of DoD's current position in biotechnology advancements; then a more detailed look into examples of potential use (exemplars) and the policy and organizational support that would be needed to bring these into fruition.

We also conclude that there are a number of significant impediments to realizing the potential that biotechnology offers the U.S. military. These include institutional, organizational, and policy issues, along with inadequate human and monetary capital.

I invite your attention to this assessment and welcome your comments on this key area of science that holds such promise for the U.S. in the future warfare environment.

A. W. MARSHALL

CHIEF OF STAFF
UNITED STATES AIR FORCE

AQ/XO

Do we have any effort in this subject?

CSAF has seen

NOV 19

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301-1200

JUL 9 8 2003

Pentagon

MEMORANDUM FOR THE AIR FORCE SURGEON GENERAL

SUBJECT: Epidemic Outbreak Surveillance (EOS) Program

I commend you and your team for their work in developing the EOS program. The attached presentation describes an effort that is consistent with the Secretary's intent for transformation of the military, and supports my commensurate objective to foster change within the Military Health System through leveraging the use of emerging, dual-use technologies.

The EOS program is a particularly compelling proposal that enhances warfighter support while providing a test-bed to validate these promising technologies. I am pleased with the success of the Zebra Chip technology, and I am confident in its potential to revolutionize clinical business practices as well as operational activities relevant to chemical and biological defense. The EOS program has my full support and I ask that you keep me informed of its progress.

William Winkenwerder, Jr., MD

Dr Marshall, OSD Dir Net Assessment, raises interest of General Jumper, USAF Chief of Staff

"Embracing biotechnology in ways beyond our current expertise in biodefense and medical applications would likely result in a strategic U.S. military advantage for the next several decades."

Dr Winkenwerder ASD Health Affairs:

(EOS presentation) … "supports my commensurate objective to foster change within the Military Health System through leveraging the use of emerging, dual-use technologies"

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EOS Real World Testbed

Basic Military Training at LAFB

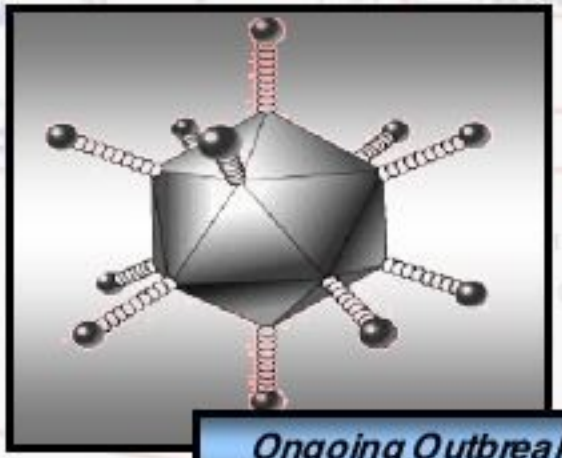
Integrate Informatics and Advanced Diagnostics

Informatics

Advanced Diagnostics

Large Isolated Population

Lose 20,000 Days/Year Outbreaks of Acute Respiratory Diseases



Ongoing Outbreaks

Level 5

Level 3

Level 1

Deliverables to meet warfighter requirements at all levels of care

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Advanced Diagnostics

EOS Operations and Deliverables

Advanced Diagnostic Platforms

Respiratory Pathogen Microarray (RPM)

Z-chip from concept to delivery
(Operational from 07 Jun 2003)
Common and biowarfare agents
Iterative design and process
Delivery, evaluation, and validation

Common Pathogens

- Adenovirus
- Influenza
- Coronavirus
- West Nile
- Parainfluenza
- RSV
- Rhinovirus
- Strept. pyogenes
- Chlam. pneumoniae
- Myco . pneumoniae
- Bord. pertussis
- Neiss. meningitidis
- Strept. pnemoniae

EOS Pathogen Pie

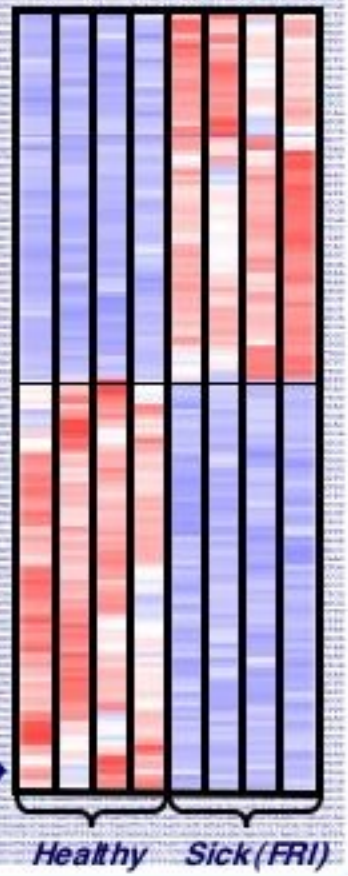
From 240,000 to 2,400,000 diagnostic tests per chip

Biowarfare Pathogens

- Smallpox
- Anthrax
- Plague
- Tularemia
- Ebola Virus
- Lassa Fever

Host Response Gene Expression Profiles

Over 30,000 human genes per test



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EOS Program Data Update

Nasal Wash and RPM Pathogen Microarray

Advanced Diagnostic Platforms

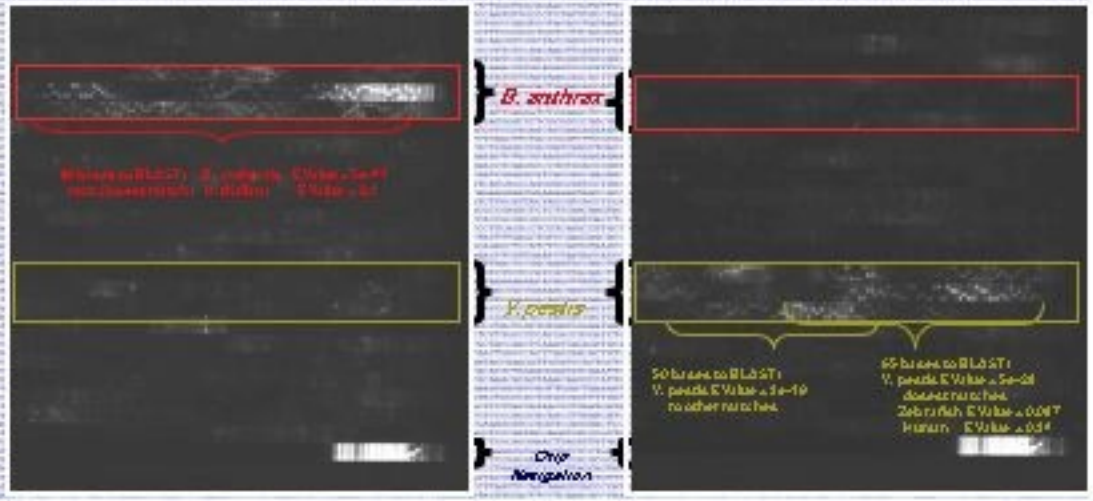
Informed Consent

Clinical Samples

Identity by PCR and Culture	#	RPM Chip Analysis Ad	Flu	Strep
Adenovirus	20	20	0	0
Influenza A	10	0	10	0
Group A Strep	9	0	0	9

100% discrimination between pathogen types and strains at level of nucleotide sequence differences - 0% likelihood of false positive

Lower limit of detection equivalent to standard PCR assays - 10 genome equivalents per 1 µl of clean sample



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EOS Bioinformatics

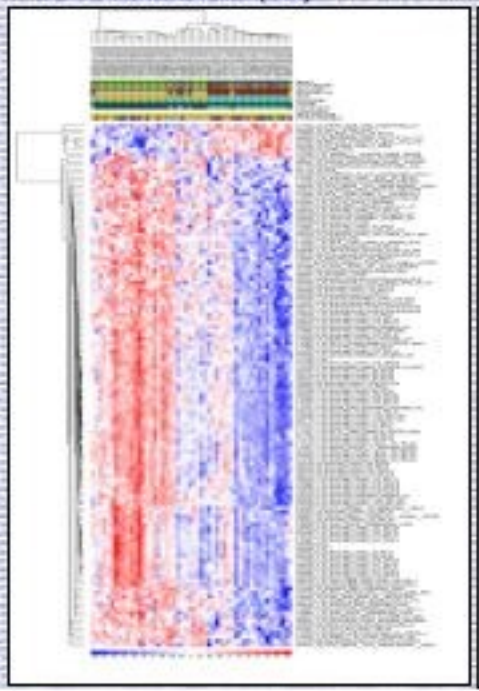
Host Leukocyte Gene Expression Profiles

Phlebotomy

PAXgene ampules

GXP Host Gene Expression	Chips
a. Installation/Training	5
b. Protocol Development	25
c. Quad 30 FRI Pilot Study	270

Healthy (30) versus Convalescent (30)



FRI-Ad4 pos (30) versus FRI-Ad4 neg (30)

EOS Group Publication

Thach et al. (2003) … Gene Expression Profiles of Blood in RNA Stabilizing Agent J Immunol Meth 283, 269-279.

Information Technology

Platform Independent - Scalable

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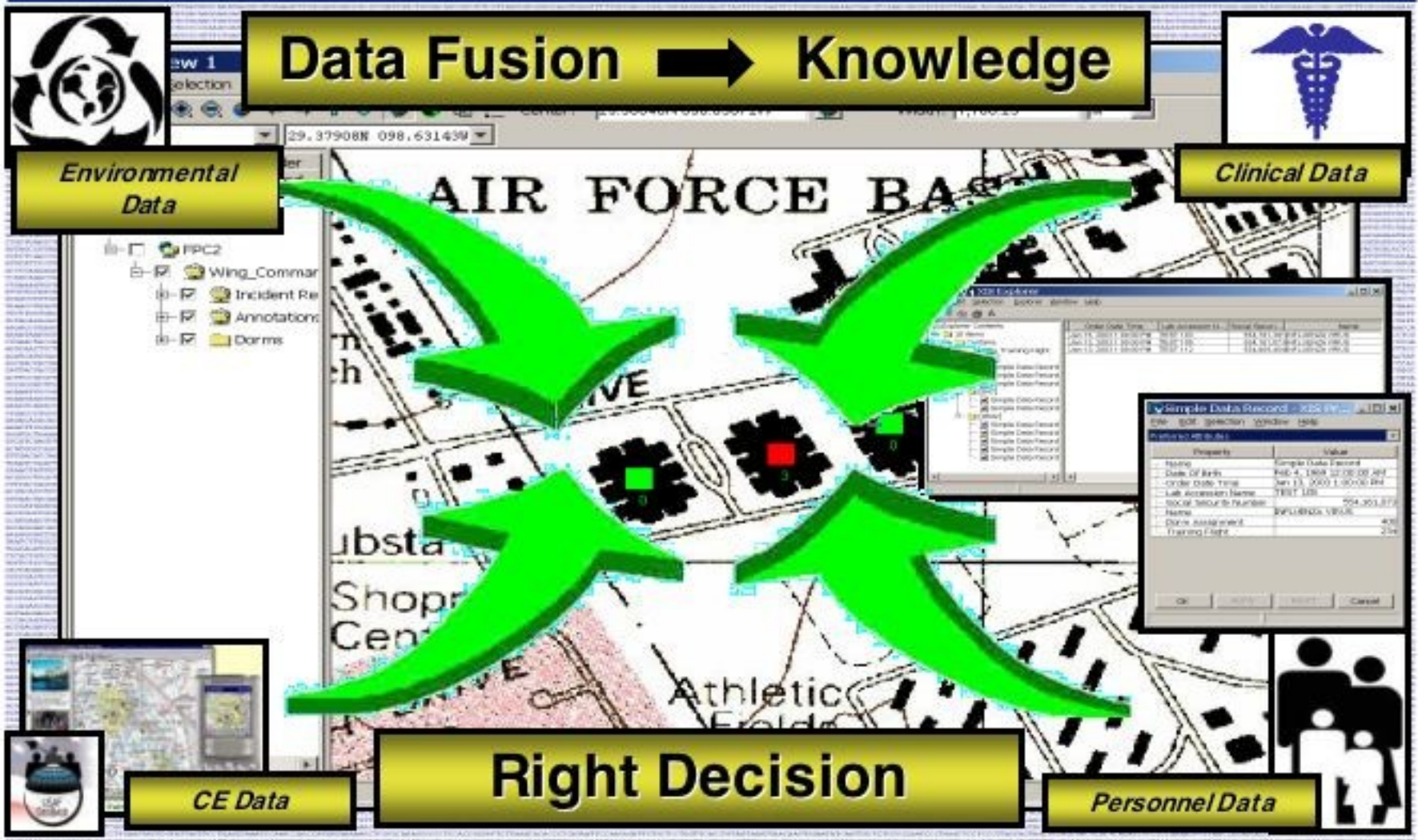

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Ethical Legal Social Issues

Balance of Mission and Policy

Key issues:

1. Must assimilate EOS system within operational healthcare to ensure capability of surveillance across entire population at risk
   - requires exhaustive FDA review and approval

2. Longitudinal tracking enables matching of personnel and assignments to minimize long-term job-related risks
   - raises personnel policy and discrimination conflicts

3. Intellectual property development within EOS program
   - requires patent review protection of US Government rights

4. Proactive address of ELSI
   - **Ensure technology and policy transition together**

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EOS Program Data Update

Advanced Surveillance Epidemiology

Pending FY03 - FY04 Funds and Network IT Implementation

2004-2005 Testbed: Ramp to Full FRI Surveillance

Installations at four dispensaries, Reid Clinic, WHMC ER and Warrior Week to engage all BMT medical encounters

Estimate 33% of all sick calls are FRI (febrile respiratory illness), about 200/month

of those, ~80% consent to nasal wash and screen

of those, ~50 % are screened on-site as likely adenovirus

remainder use blood, nasal wash specimens for Dx microarray analysis

2004-2005 Advanced Epidemiology: Baseline Gene Expression DB

Initiate data acquisition for baseline healthy BMT gene expression profiles

Longitudinal tracking of individuals from health incoming through FRI and recovery

Identify and track asymptomatic close-contacts of FRI patients (exposed individuals)

Execute pilot environmental surface sampling for adenovirus and influenza

Projected Assays (12 months):

	Surveillance	Epidemiology
RAPIDS (PCR)	1,180	900
Pathogen Chip (RPM)	236	290
Host Chip (GXP)	177	1,040

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Epidemic Outbreak Surveillance

Contributing to Mission Success

Scheduling

Operations

Epidemic Containment

Command and Control

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Dual Use in Operational Medicine

Military and Civilian Venues

Clinical Medicine

Modernization

Improving Health Care and Decreasing C

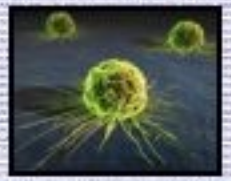
Occupational Toxicology

- Identify acute high level and chronic low level exposures
- Bioeffects monitoring
- Chromate, JP-8 and other TICs/TIMs

Cancer

Individualize therapy based on molecular information

gleevec imatinib mesylate



Bioterrorism - Biowarfare

- What's Next? Natural or adversarial agents?
- Health Surveillance Biodefense System
- Integrated Diagnostics Integrated Informatics
- Embedded within operational medicine
- Real-time decision quality information for CC and POC

Headquarters U.S. Air Force

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AFMS FY06-11 POM Bills and Offsets Final Prioritization

21 July 04
Mr. Chet Gooding, GS-15
Deputy Director
Medical Plans and Programs
Gooding.chet@pentagon.af.mil

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FY06 POM Bills/Offset in Review

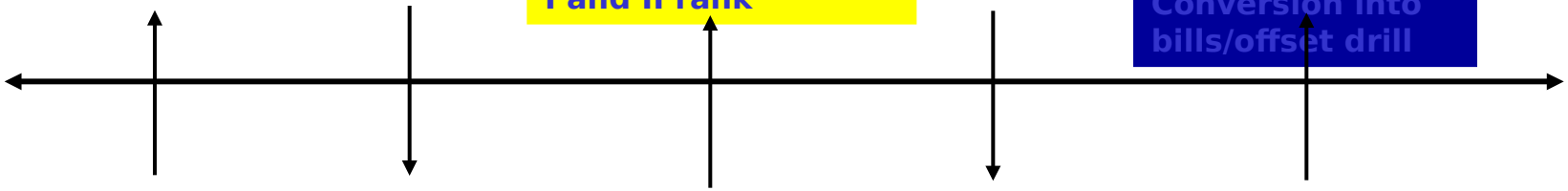
31 March – Group's original ranking of AFMS Bills/Offsets

21 May – Group relooks Bills/Offsets post POM Fiscal Guidance (MTF efficiencies/Local Support)

2 June – Group recommends revised ranking after review- reverses Mod Block I and II rank

8 July – Group recommendation presented to AFMS Council— Council returns to Group with request to "fix" Modernization

21 Jul – "Fix" Modernization and incorporate Local Support increment & Mil/Civ Conversion into bills/offset drill



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Initial Recommendation (As of 31 March 2004)

Rank	Corporate Bills	Amt	Cumulative
1	Dental Central Contract	2,540	2,540
2	HAWC Contractors	5,400	7,940
3	OB Contract Bill	16,300	24,240
4	HPSP (dental option included)	4,182	28,422
5	HPSP (Block II Increase)	3,964	32,386
6	Referral Mgmt Centers	4,520	36,906
7	MMSO	2,000	38,906
8	Modernization delta	21,000	59,906
9	Pt Movement Items	1,530	61,436
10	HPLRP	7,602	69,038
11	HPSP (Block III Increase)	3,100	72,138
12	Referral Mgmt Centers (Block II Increase)	880	73,018
13	Modernization (Block II Increase)	4,920	77,938
14	HPLRP (Block II Increase)	2,370	80,308
15	Referral Mgmt Centers (Block III Increase)	3,260	**83,568**

Rank	Offsets	Amt	Cumulative
15	Tradespace	-46,626	-46,626
14	Block I Offsets	-18,800	-65,426
13	TDY Block II	-255	-65,681
12	Contracts Block II	-5,751	-71,432
11	TDY Block III	-1,799	-73,231
10	IM/IT Block II	-1,824	-75,055
9	Supplies Block II	-1,402	-76,457
8	Equipment Block II	-2,233	-78,690
7	IM/IT Block III	-689	-79,379
6	Supplies Block III	-4,632	**-84,011**

Recommendations used to complete POM Options

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Bills/Offsets Presented to Group 2 June 04

Starting Rank	Revised Rank	Corporate Bills	$126,481	FY06 Increment	FY06 Cumulative
1	1	MTF Effciencies	$ 92,923	33,558	33,558
2	2	Dental Central Contract	$ 90,383	2,540	36,098
3	3	HAWC Contractors	$ 84,983	5,400	41,498
4	4	OB Contract Bill	$ 68,683	16,300	57,798
5	5	HPSP (dental option included)	$ 64,501	4,182	61,980
6	6	HPSP (Block II Increase)	$ 60,537	3,964	65,944
11	7	Appointing Block I	$ 52,157	8,380	74,324
7	8	Referral Mgmt Centers Block I	$ 48,057	4,100	78,424
10	9	HPLRP	$ 40,455	7,602	86,026
12	10	Medical Management Block I	$ 29,040	11,415	97,441
9	11	Pt Movement Items	$ 27,510	1,530	98,971
14	12	DoD/MERB	$ 25,310	2,200	101,171
19	13	Modernization (Block II Increase)	$ 20,390	4,920	106,091
16	14	HPSP (Block III Increase)	$ 17,290	3,100	109,191
18	15	Referral Mgmt Centers (Block II Increase)	$ 12,730	4,560	113,751
8	16	Modernization delta	$ (8,270)	21,000	134,751
20	17	HPLRP (Block II Increase)	$(10,640)	2,370	137,121
23	18	Pt Movemement Items (Block II Increase)	$(13,670)	3,030	140,151
22	19	Modernization (Block III Increase)	$(30,150)	16,480	156,631
24	20	HPLRP (Block III Increase)	$(32,613)	2,463	159,094
25	21	Pt Movement Items (Block III Increase)	$(36,553)	3,940	163,034
15	22	Medical Management Block II	$(44,097)	5,062	168,096
26	23	Medical Management Block III	$(39,035)	2,482	170,578
27	24	Pharmacy Block II	$(56,420)	12,323	182,901
28	25	OP	$(74,820)	18,400	201,301
17	26	Pharmacy (Buckley Only)	$(81,020)	6,200	207,501
13		Appointing Block II		0	207,501
21		Referral Mgmt Centers (Block III Increase)		0	207,501

Rank*	Offsets	Amt	Cumulative
15	Tradespace	-46626	-46,626
14	Block I	-18800	-65,426
13	TDY Total	-255	-65,681
12	Contracts Total	-5,751	-71,432
11	TDY Total	-1,799	-73,231
10	IM/IT Total	-1824	-75,055
9	Supplies Total	-1,402	-76,457
8	Equipment Total	-2,233	-78,690
7	IM/IT Total	-689	-79,379
6	Supplies Total	-4,632	-84,011
5	Contracts Total	-15,828	-99,839
4	Equipment Total	-1,614	-101,453
3	SRM Total	-3,714	-105,167
2	Pharmaceuticals Total	-328	-105,495
1	SRM Total	-3,986	-109,481
0	Additional Tradespace	-17,000	-126,481

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Offsets Post DHP POM Results

Rank*	Offsets	Amt	Cumulative
15	Tradespace	-46626	-46,626
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13	TDY Total	-255	-65,681
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4	Equipment Total	-1,614	-101,453
3	SRM Total	-3,714	-105,167
2	Pharmaceuticals Total	-328	-105,495
1	SRM Total	-3,986	-109,481
0	Additional Tradespace	-17,000	-126,481
0	FY06 Local Support	-11,394	-137,875
0	FY06 Mil To Civ Con	-6,467	-144,342

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The Way Ahead?

- Re-look Medical Modernization Blocks I and II Priority
  - Apply correct label to Med Mod Block I
- Apply Local Support Funding/Mil to Civ Savings
  - Buy next two bills (HPLRP Block II and Patient Movement Block II) in full and part of Med Mod Block III
  - Or buy back offsets in priority order (SRM Block III, SRM Block II, Pharmacy, and Equipment)
  - Or buy back combination of bills and offsets
- Present to AFMS Council
- Lay-in MAJCOM/Panel TOA

Bills and Offsets Review

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Starting Rank	Revised Rank	Corporate Bills	$144,342	FY06 Increment	FY06 Cumulative
1	1	MTF Efficiencies	$110,784	33,558	33,558
2	2	Dental Central Contract	$108,244	2,540	36,098
3	3	HAWC Contractors	$102,844	5,400	41,498
4	4	OB Contract Bill	$ 86,544	16,300	57,798
5	5	HPSP (dental option included)	$ 82,362	4,182	61,980
6	6	HPSP (Block II Increase)	$ 78,398	3,964	65,944
11	7	Appointing Block I	$ 70,018	8,380	74,324
7	8	Referral Mgmt Centers Block I	$ 65,918	4,100	78,424
10	9	HPLRP	$ 58,316	7,602	86,026
12	10	Medical Management Block I	$ 46,901	11,415	97,441
9	11	Pt Movement Items	$ 45,371	1,530	98,971
14	12	DoD/MERB	$ 43,171	2,200	101,171
19	13	Modernization (Block II Increase)	$ 38,251	4,920	106,091
16	14	HPSP (Block III Increase)	$ 35,151	3,100	109,191
18	15	Referral Mgmt Centers (Block II Increase)	$ 30,591	4,560	113,751
8	16	Modernization Block I (EOS)	$ 9,591	21,000	134,751
20	17	HPLRP (Block II Increase)	$ 7,221	2,370	137,121
23	18	Pt Movemement Items (Block II Increase)	$ 4,191	3,030	140,151
22	19	Modernization (Block III Increase)	$(12,289)	16,480	156,631
24	20	HPLRP (Block III Increase)	$(14,752)	2,463	159,094
25	21	Pt Movement Items (Block III Increase)	$(18,692)	3,940	163,034
15	22	Medical Management Block II	$(23,754)	5,062	168,096
26	23	Medical Management Block III	$(26,236)	2,482	170,578
27	24	Pharmacy Block II	$(38,559)	12,323	182,901
28	25	OP	$(56,959)	18,400	201,301
17	26	Pharmacy (Buckley Only)	$(63,159)	6,200	207,501
13		Appointing Block II		0	207,501
21		Referral Mgmt Centers (Block III Increase)		0	207,501

Rank*	Offsets	Amt	Cumulative
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2	Pharmaceuticals Total	-328	-105,495
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0	Additional Tradespace	-17,000	-126,481
0	FY06 Local Support	-11,394	-137,875
0	FY06 Mil To Civ Con	-6,467	-144,342

History of OP Requirement

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- 25 Feb AFMS Group
  - Not presented as radioactive issue at Leesburg
  - $50.4M shortfall in FY04-11
- 26 Mar AFMS Group
  - SGMP briefed wedge for OP included on list of external bills (Unfunded Requirements)
- 14 Apr AFMS Group
  - Discussed OP status as external vs. internal bill
  - Decision made to retain as external bill
- 21 May AFMS Group
  - Presented proposal to streamline external bills list to include only: Dod/MERB, Local Support, and Pharmacy

History of OP Requirement

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- 21 May AFMS Group (Cont'd)
  - Support Panel protested
  - Agreement reached to rack and stack OP requirement with Internal bills
- 2 June AFMS Group
  - OP was included on internal bills list but fell below cutline during priority ranking of bills

History of OP Requirement

U.S. AIR FORCE

Starting Rank	Revised Rank	Corporate Bills	$126,481	FY06 Increment	FY06 Cumulative
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4	4	OB Contract Bill	$ 68,683	16,300	57,798
5	5	HPSP (dental option included)	$ 64,501	4,182	61,980
6	6	HPSP (Block II Increase)	$ 60,537	3,964	65,944
11	7	Appointing Block I	$ 52,157	8,380	74,324
7	8	Referral Mgmt Centers Block I	$ 48,057	4,100	78,424
10	9	HPLRP	$ 40,455	7,602	86,026
12	10	Medical Management Block I	$ 29,040	11,415	97,441
9	11	Pt Movement Items	$ 27,510	1,530	98,971
14	12	DoD/MERB	$ 25,310	2,200	101,171
19	13	Modernization (Block II Increase)	$ 20,390	4,920	106,091
16	14	HPSP (Block III Increase)	$ 17,290	3,100	109,191
18	15	Referral Mgmt Centers (Block II Increase)	$ 12,730	4,560	113,751
8	16	Modernization delta	$ (8,270)	21,000	134,751
20	17	HPLRP (Block II Increase)	$(10,640)	2,370	137,121
23	18	Pt Movemement Items (Block II Increase)	$(13,670)	3,030	140,151
22	19	Modernization (Block III Increase)	$(30,150)	16,480	156,631
24	20	HPLRP (Block III Increase)	$(32,613)	2,463	159,094
25	21	Pt Movement Items (Block III Increase)	$(36,553)	3,940	163,034
15	22	Medical Management Block II	$(44,097)	5,062	168,096
26	23	Medical Management Block III	$(39,035)	2,482	170,578
27	24	Pharmacy Block II	$(56,420)	12,323	182,901
28	25	OP	$(74,820)	18,400	201,301
17	26	Pharmacy (Buckley Only)	$(81,020)	6,200	207,501
13		Appointing Block II		0	207,501
21		Referral Mgmt Centers (Block III Increase)		0	207,501

Presented to AFMS Council in 8 Jul 04 POM Brief

Meeting Recap & Calendar

U.S. AIR FORCE

- New Items
- Action Items
- Meeting Schedule:
  - AFMS Group: Wed., 28 Jul, 1300-1530